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the Decision Board for Early Breast Cancer

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13. ABSTRACT (Maximum 200 Words) Women with breast cancer have indicated their desire to be involved in decisions about their care. We have developed a decision aid, called the Decision Board for women regarding choices in breast cancer with respect to surgical treatment and the use of adjuvant chemotherapy. Randomized trials have demonstrated that the Decision Board not only increases patient knowledge, but improves patient satisfaction, decreases decisional conflict, and facilitates a shared decision-making between the oncologist and the patient. This present study builds on previous work and involves the development of different versions of the Decision Board using different types of media in order to improve the effectiveness of these instruments and to facilitate their wider use in the community. . Two new versions have been produced: a computer-based version, which is presented on a laptop computer, and an easy-to-use paper-based version. These versions are currently being compared with a standard poster size foam-core version in a randomized trial. Important outcomes will include patient comprehension and acceptability. Newer versions of the Decision Board that are easier to use and present will lead to wider use in the community resulting in more knowledgeable and satisfied breast cancer patients.				
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Introduction

The main objective of this study is to further enhance information transfer between the doctor and the patient, giving women with early stage breast cancer an opportunity to more fully participate in treatment decision-making. The study compares three versions of the decision board (DB), all containing the same information but using different forms of media. The three versions of DBs are: (i) the standard DB, which is a foam core, poster sized version with pull-out panels; (ii) the computer DB, which uses a Window's based program that resembles the standard DB and is available on a laptop computer; (iii) the paper DB, which is a small 8.5 in. x 11 in. paper version of the standard DB and also serves as the take-home brochure for the standard DB. Patients are randomly assigned to one of three versions of the DB when they attend their physician's office for consultation. The DB presents one of two treatment choices: (i) an adjuvant chemotherapy decision for women with moderate risk node-negative breast cancer (no chemotherapy vs. CMF (Cyclophosphamide, Methotrexate, and Fluorouracil) vs. AC (Adriamycin and Cyclophosphamide)). This stratum involving the chemotherapy decision is called DECIDE-C, (ii) a surgical decision (mastectomy vs. lumpectomy plus radiation) for women with Stage I or II breast cancer. This stratum involving the surgical decision is called DECIDE-S. The trial is currently open and accruing patients. The plan is to complete accrual to the study by February 29, 2004 and submit a final report for May 2004.

Body

Progress made towards meeting objectives since the last review is outlined below. The stratum of the trial involving the chemotherapy DB (DECIDE-C) has been actively recruiting patients since accrual was opened on April 29, 2002. The stratum of the trial involving the surgical DB (DECIDE-S) started on February 17, 2003. Both parts of the trial are running smoothly.

Task 1: Development of Computer-based Version of Decision Boards and Updating the Standard Versions of the Decision Boards Currently Used at the HRCC and Outlying Communities: Completed.

Completed, see previous reports.

Task 2: Start up of the RCT. Development of Operations Manuals, Data Forms, Training of Clinicians to use Computer-Based Versions: Completed.

The case report forms (CRFs) for the DECIDE-S stratum were finalized to ensure that patients on the DECIDE-S and DECIDE-C trials completed similar forms. The CRFs gathering comprehension information were developed to be similar in design and format with 32 True/False questions (regarding the different treatment options) and three multiple-choice questions (regarding risk), however, the content is different due to the differing topics of the DECIDE-C and DECIDE-S strata. Both instruments are modifications of

previous questionnaires validated in two separate RCTs designed to evaluate the chemotherapy and surgery DBs^{1,2}.

Eight surgeons were recruited to the DECIDE-S study since the last report. These surgeons have their practices in Hamilton, Brantford, Guelph, Simcoe, St. Catharines and Welland, Ontario. Prior to the surgeon accruing their first patient, the Research Coordinator and Research Assistant visited their office for a "start-up" meeting. At this "start-up" meeting the surgeon was shown how to properly present each of the three versions of the DB. The nurse or receptionist working with each surgeon was present during this presentation so that they could understand what the study involves. The procedures for randomizing a patient to the study were discussed, including obtaining informed consent from the patient. A cell phone was obtained strictly for the DECIDE-S study, as surgeons were concerned about increasing the length of visits with the patient if they had to page the SCCR Unit and wait for a response. Having the cell phone makes the randomization process fast and efficient. As the patient entered onto the DECIDE-S trial is not seen directly by the SCCR Unit research staff, information packages were created for the patient to take home with them. These packages contain the take-home version of the DB, the Baseline and the 1-week CRFs. An instruction sheet is included in this package to explain how and when to complete the questionnaires. Six take-home packages, all in colour-coded folders to clearly identify the appropriate package for each patient, were created for each version of the DB (standard, computer, paper) and whether the patient had information presented about axillary node dissection. To check that patients receive the proper take-home package, the nurse or receptionist are told which

colour folder the patient should receive at the time of the randomization phone call. Three and six-month questionnaires are then mailed to the patient.

Task 3: Patient Recruitment and Data Collection: In Progress.

Patient recruitment to DECIDE-C started on April 29, 2002 with the first patient randomized on May 8, 2002. There are currently 98 patients randomized to the trial by six Medical Oncologists. The current rate of accrual is 6 patients per month.

It was decided to open DECIDE-S in two local surgeons offices first to identify any unforeseen problems. The process ran very smoothly, therefore more surgeons were approached to take part in the study. There are currently 8 surgeons recruiting patients to the study, with 2 surgeons joining in October 2003. The addition of these new surgeons should boost accrual, which currently sits at 28. We anticipate reaching our target sample size of 200 patients for both strata in DECIDE-C and DECIDE-S by February 2004.

Task 4: Data Entry and Analyses: In Progress.

The trial databases (both the study database and the trial management database) were modified to collect information for DECIDE-S. The study database was set up to hold the information collected on the CRFs. Programs were written to ensure correct data entry as a quality control measure. Data entry is up to date on the study.

The Trial Management System (TMS) was designed to help keep track of patient visits and the timeliness of the collection of the CRFs. The TMS generates a number of monthly reports that indicate how the trial is doing in terms of patient accrual, CRF completion, overdue assessments, upcoming visits, and data entry (Appendix 1). These reports help to ensure that the trial runs smoothly, no visits are missed, and all CRFs are collected in a timely fashion.

Key Research Accomplishments

Year 5

- ◆ Start-up of the randomized control trial of DECIDE-S
- ◆ Revised the case report forms to ensure the DECIDE-C and DECIDE-S forms were compatible
- ◆ Created the Study Database
- ◆ Created the Trial Management Database
- ◆ Continued to accrue patients to the DECIDE-C study at an acceptable rate

Year 4

- ◆ Start-up of the randomized controlled trial of DECIDE-C
- ◆ Added paper version as a third treatment arm
- ◆ Enabled node-positive patients to enter (if not competing with other clinical trials)
- ◆ Added more personalized features to DECIDE-C board
- ◆ Revised the DECIDE-S version of the decision board based on feedback from the DECIDE-C version
- ◆ Created the Study Database and started data entry
- ◆ Created the Trial Management Database

Year 3

- ◆ Updated the standard version of the node-negative Decision Board
- ◆ Revised the computer version of the node-negative Decision Board
- ◆ Field testing of the computer version of the node-negative Decision Board was completed
- ◆ Completed field testing of the computer version of the node-negative Decision Board

Year 2

- ◆ Completed field testing of the computerized version of the surgery Decision Board
- ◆ Developed prototype of the computerized version of the node-negative Decision Board
- ◆ Completed field testing of the standard version of the node positive Decision Board
- ◆ Developed a prototype of the computerized version of the node-positive Decision Board
- ◆ Field testing of the computerized version of the node-positive Decision Board
- ◆ Field testing of the computerized version of the node-negative Decision Board

Year 1

- ◆ Completed a review of the literature and updated the standard version of the surgery Decision Board
- ◆ Completed a review of the literature and updated the standard version of the node-positive Decision Board
- ◆ Completed a review of the literature and updated the standard version of node-positive Decision Board
- ◆ Developed the computerized version of the surgery Decision Board

Reportable Outcomes

Publications:

Peer Reviewed Publications:

1. Whelan TJ, Sawka C, Levine M, Gafni A, Reyno L, Willan A, Julian J, Dent S, Abu-Zahra H, Chouinard E, Tozer R, Pritchard K, Bodendorfer I. Helping patients make informed choices: A randomized trial of a decision aid for adjuvant chemotherapy in lymph node-negative breast cancer. *Journal of the National Cancer Institute* 2003; 95:581-587.
2. Charles CA, Whelan T, Gafni A, Farrell S, Willan A. The meaning of shared decision-making to physicians treating women with breast cancer. *Journal of Clinical Oncology* 2003; 21:932-936.
3. Elit L, Charles C, Golf I, Gafni A, Farrell S, Tedford S, Dal Bello D, Whelan T. Women's perceptions about treatment decision making for ovarian cancer. *Gynecologic Oncology* 2003; 88:89-95.

Journal Articles Submitted for Publication:

1. Charles C, Gafni A, Whelan T. Barriers, facilitators and strategies to promote shared decision-making among cancer physicians and patients. Submitted to *Health Expectations*, August, 2003.
2. Charles C, Gafni A, Whelan T. Self reported use of shared decision making among physicians who treat women with newly diagnosed breast cancer. Submitted to *Health Expectations*, July 2003.

Abstracts:

1. Whelan T, Levine M, Gafni A, Julian J, Chamber S, O'Brien MA, Sebaldt R, Tozer R, Sanders K, Reid S. Development and Evaluation of Different Versions of the Decision Board for Early Breast Cancer (DECIDE). Accepted at the CBCRI Reasons for Hope Annual Meeting, Ottawa, October 25-27, 2003.
2. Whelan T, Levine M, Gafni A, Willan A, Sanders K, Mirsky D, Chambers S, O'Brien MA, Dubois S, Reid S. Empowering Women and Their Physicians with the Evidence: A Randomized Trial of a Decision Board for Breast Cancer Surgery. Accepted for Oral Presentation to the 2nd International Shared Decision Making Conference, Singleton Park, Swansea, Wales, UK, September 2-4, 2003.

3. Whelan T, Levine M, Sanders K, Gafni A, Willan A, Mirsky D, Chambers S, O'Brien MA, Dubois S, Reid S. Empowering Women and Their Physicians with the Evidence: A Randomized Trial of a Decision Board for Breast Cancer Surgery. Accepted for Oral Presentation at ASCO 39th Annual Meeting, Chicago, IL, May 31-June 3, 2003.

Conference Proceedings:

1. Whelan T. Empowering Women and Their Physicians with the Evidence: A Randomized Trial of a Decision Board for Breast Cancer Surgery. Proceedings of the American Society of Clinical Oncologists (ASCO) 39th Annual Meeting, Chicago, Illinois, 2003.

Conclusions

The DECIDE-C accrual is well on its way to meeting the target of 100 patients with 98 patients currently randomized, while the DECIDE-S trial has started recruitment with 28 patients accrued. New surgeons have just joined DECIDE-S so recruitment should soon increase. We anticipate reaching our target sample size of 200 patients in total for both strata by February 2004.

Both a study database and a management database were set up for the DECIDE-S study to correspond with similar databases for the DECIDE-C study and data entry is up to date.

References

1. Whelan TJ, Sawka C, Levine M, Gafni A, Reyno L, Willan A, Julian J, Dent S, Abu-Zahra H, Chouinard E, Tozer R, Pritchard K, Bodendorfer I. Helping patients make informed choices: A randomized trial of a decision aid for adjuvant chemotherapy in lymph node-negative breast cancer. *Journal of the National Cancer Institute* 2003; 95:581-587.
2. Whelan T, Levine M, Sanders K, Gafni A, Willan A, Mirsky D, Chambers S, O'Brien MA, Dubois S, Reid S. Empowering Women and Their Physicians with the Evidence: A Randomized Trial of a Decision Board for Breast Cancer Surgery. Presented at the ASCO 39th Annual Meeting, Chicago, IL, May 31-June 3, 2003.

Appendices

Appendix 1. Trial Management Reports

Evaluation of Different Versions of the Decision Board (DECIDE-S)

Projected Follow-up Schedule, by Patient ID for 01 Oct 2003 - 30 Nov 2003

Centre: Dr. Barbara Heller

PATIENT STUDY ID	PATIENT INITIALS	ASSESSMENT	TARGET DATE
506	A D	3 Month Assessment	11 Oct 2003
518	C L	3 Month Assessment	19 Nov 2003
520	C L	3 Month Assessment	10 Oct 2003

3 visits

Evaluation of Different Versions of the Decision Board (DECIDE-S)

Patient Assessment Summary as of 30 Sep 2003

Centre: Dr. Barbara Heller

Assessment	Completed		Pending		Overdue		Missed		Total
	count	%	count	%	count	%	count	%	
Baseline Assessment	7	100.0	0	0.0	0	0.0	0	0.0	7
1 Week Assessment	6	85.7	1	14.3	0	0.0	0	0.0	7
3 Month Assessment	0	0.0	0	0.0	1	100.0	0	0.0	1
6 Month Assessment	0	0.0	0	0.0	0	0.0	0	0.0	0

Evaluation of Different Versions of the Decision Board (DECIDE-S)

List of Overdue Assessments as of 30 Sep 2003

Centre: Dr. Barbara Heller

Patient Study ID	Patient Initials	Projected Assessment Date	Assessment
501	C S	11 Sep 2003	3 Month Assessment